

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Smith et al.

Serial No.: 10/804,331

Filed: March 19, 2004

For: ***ALPHAVIRUS REPLICONS AND HELPER CONSTRUCTS***

Confirmation No.: 7017

Group Art Unit: 1648

Examiner: B. Blumel

Date: April 9, 2008

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

COMMUNICATION

Sir:

This Communication is being submitted pursuant to telephone correspondence between Examiner Benjamin Blumel and applicants' representative, Dr. Mary Miller, on April 7, 2008. Specifically, pending claims 1-6, 9-10, 11-14, 16, 19, 21, 23-36, 58 and 59 were rejected in the September 21, 2007 Office Action as allegedly either anticipated by, or obvious in view of, U.S. Patent Publication No. 2003/0148262 (Polo et al.). As discussed on April 7, 2008, as well as during a January 15, 2008 personal interview of this application with Examiner Blumel and supervisory Examiner Bruce Campbell, Polo et al. can be distinguished from the claimed invention for the following reasons.

Independent claims 1 and 58 are directed to a recombinant replicon nucleic acid comprising, among other elements, an alphavirus subgenomic promoter-IRES-heterologous nucleic acid of interest (NOI) cassette, which is in 5' to 3' orientation. Independent claims 19 and 61 are directed to a recombinant replicon nucleic acid comprising, among other elements, an alphavirus subgenomic promoter-IRES-heterologous nucleic acid of interest (NOI) cassette, said cassette further comprising a spacer non-coding nucleic acid 3' to the alphavirus subgenomic promoter and 5' to the IRES.

Independent claim 48 is directed to a recombinant nucleic acid comprising, among other elements, an alphavirus subgenomic promoter-IRES-heterologous NOI cassette, which is in 5' to 3' orientation, wherein the NOI encodes one or more alphavirus structural proteins. Independent claim 52 is directed to a recombinant nucleic acid comprising, among other elements, an

alphavirus subgenomic promoter-IRES-heterologous NOI cassette, said cassette further comprising a spacer non-coding nucleic acid 3' to the alphavirus subgenomic promoter and 5' to the IRES, wherein the NOI encodes one or more alphavirus structural proteins.

Polo et al. discloses a replicon RNA comprising, among other elements, a "means to express one or more heterologous sequences, such as for example an IRES or a viral (e.g., alphaviral) subgenomic promoter...." (See, e.g., paragraph 0056). Polo et al. also discloses a defective helper RNA that contains a means to express alphavirus structural protein(s), which is described to be "a viral (e.g., alphaviral subgenomic promoter..., or alternatively some other means to effect expression of the alphavirus structural protein (e.g., internal ribosome entry site, ribosomal readthrough element)." (See, e.g., paragraph 0059). Thus, it would be understood by one of ordinary skill in the art that Polo et al. describes the use of either an alphaviral subgenomic promoter OR an IRES in the replicon and helper RNAs described therein.

In contrast, all of the independent claims of this invention recite an alphavirus subgenomic promoter-IRES-heterologous nucleic acid of interest (NOI) cassette, which is in 5' to 3' orientation, or an alphavirus subgenomic promoter-IRES-heterologous NOI cassette, said cassette further comprising a spacer non-coding nucleic acid 3' to the alphavirus subgenomic promoter and 5' to the IRES. Thus, it would be understood by one of ordinary skill in the art that in the invention claimed herein, both a 26S promoter AND an IRES are provided, along with a heterologous NOI, in the same cassette, in 5' to 3' orientation. This claimed cassette, comprising this combination of elements in this order, is not taught or suggested in Polo et al.

Furthermore, the cited secondary references fail to make up the deficiencies of Polo et al. because none of the secondary references teach or suggest the claimed cassette.

For at least these reasons, applicants believe that these rejections of the pending claims in the September 21, 2007 Office Action have been overcome and respectfully request the withdrawal of these rejections.

Additionally provided herewith for the Examiner's reference is a copy of each of four slides that were discussed during the January 15, 2008 personal interview, as requested.

Attorney Docket No.: 9368-5

Serial No.: 10/804,331

Filed: March 19, 2004

Page 3 of 3

No fee is believed due with this Communication. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

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Respectfully submitted,



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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on April 9, 2008.

Signature: _____

Claire Wimberly

